

Rejection of Claims 1-4 under 35 U.S.C. §103(a):

The Examiner has maintained the rejection of claims 1-4 under 35 U.S.C. §103(a) “as being unpatentable over Cuevas et al. (Eur. J. Med. Res., Vol. 2, pages 465-468, November, 1997) in view of Datta et al. (Cell, Vol. 91, pages 231-241, October, 1997). Claim 5 remains objected to for the reasons of record in Paper No. 13, page 5.

Applicants respectfully reiterate the arguments previously presented in response to the outstanding Office Action and, further, submit herewith the Declaration of Kenneth Walsh under 37 CFR 1.131 to remove the cited references as prior art against the claimed invention. In view of this submission, Applicants respectfully request withdrawal of the rejection of claims under 35 U.S.C. 103.

The claimed invention is directed to a method for treating myocardial infarction by administering an Akt molecule. This invention is described in the first paragraph of the Summary of the Invention (application page 2, lines 16-22):

“The invention involves the discovery that Akt (also known as Protein Kinase-B, PKB) inhibits apoptotic cell-death of cells, and in particular, inhibits apoptotic cell-death of cardiomyocytes, skeletal myocytes and/or vascular endothelial cells. In view of these discoveries, it is believed that Akt molecules can be used to inhibit apoptotic cell-death of the afore-mentioned cell types, and in particular, to treat conditions (e.g., myocardial infarction) that result in increased apoptotic cell-death of cardiomyocytes, skeletal myocytes and/or vascular endothelial cells.”

The purpose of the Walsh Declaration submitted herewith is to establish conception and diligence in reduction to practice of the claimed invention in the United States as of a date prior to October 17, 2001, which is the publication date appearing on the S. Datta et al. reference, entitled “Akt Phosphorylation of BAD Couples Survival Signals to the Cell-Intrinsic Death Machinery” (Cell, vol. 91:231-241 (October 17, 1997), made of record by the Examiner during prosecution of this application.

To establish conception of the claimed invention, the Walsh Declaration includes Exhibit A which is a reproduction of two pages from the laboratory notebook of Yasushi Fujio. Mr. Fujio worked in Dr. Walsh’s laboratory under his direction on research relating to the claimed invention. The Exhibit A notebook pages (entitled “C2C12 cells 1” and C2C12 cells 2,” dated

"971116" and "971119," respectively, top right hand corner of pages, year/month/day), describe the results of experiments which establish that Akt inhibits apoptotic cell-death of myocytes.

The experimental strategy for the Exhibit A experiment is presented in Example 1 of the application as filed (pages 32-40, "Akt controls skeletal myocyte viability"). Example 1 of the application further describes the materials and methods that are identified in Exhibit A (e.g., "C2C12 cells" (page 33, line 10); "Lipofectamine" (page 34, line 30); "OptiMEM" (page 34, line 30); "CMV" (page 35, line 11, "cytomegalovirus promoter"); " β -Gal" (page 35, line 17, " β -galactosidase"); "Akt(wt)" (page 35, line 22, "wild-type Akt"); and "Akt(K179M)" (page 35, line 23). The results shown in Exhibit A (page 2 table and bar graph) also are described in Example 1 of the application as filed, "... these data show that Akt is effective in protecting mitotic cells against death during the differentiation process" (page 40, lines 1-2).

The pending application is substantially identical to the provisional application (USPN 60/102,740, filed October 2, 1998, copy enclosed) to which priority is claimed. To show diligence between conception and the filing date of the priority document, the Walsh Declaration further includes Exhibit B, which shows a reproduction of four additional laboratory notebook pages of Mr. Fujio relating to experiments conducted using endothelial cells and cardiomyocytes. These notebook pages are entitled "Endothelial cell 1", "Endothelial cell 2", "cardiomyocyte 1", and "cardiomyocyte 2", with the earliest dates for these pages being "960407" for the endothelial cell experiments and "980630" for the cardiomyocytes, respectively (top right hand corner of pages, year/month/day). These experiments describe the results of experiments which establish that Akt inhibits apoptotic cell-death of endothelial cells and cardiomyocytes, respectively.

The Walsh Declaration and, in particular, Exhibit A thereof, establishes a date of conception of the invention prior to October 17, 1997, which is the publication date appearing on the S. Datta et al. reference.

The Walsh Declaration and, in particular, Exhibit B thereof, together with the filing of the above-identified application and its priority document, establish due diligence in reducing the invention to practice from a date prior to the publication date appearing on the S. Datta et al. reference to the filing date of the above-identified patent application priority document.

Applicants respectfully submit that the Walsh Declaration evidence submitted herewith is sufficient to remove the cited references as prior art against the claimed invention.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-4 under 35 U.S.C. §103(a) in view of the cited art.

Claim Objection:

Claim 5 is objected to as being dependent upon a rejected base claim. Applicants appreciate that the Examiner has found the claim 5 allowable over the prior art of record; however, Applicants have elected not to rewrite this claim in independent form in view of the previously-submitted arguments in favor of the patentability of the base claim and the Walsh Declaration submitted herewith.

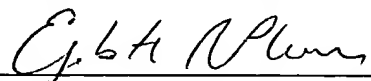
Summary:

Applicants believe that each of the pending claims now is in condition for allowance. Applicants respectfully request that the Examiner telephone the undersigned attorney in the event that the claims are not found to be in condition for allowance.

If the Examiner has any questions and believes that a telephone conference with Applicant's attorney would prove helpful in expediting the prosecution of this application, the Examiner is urged to call the undersigned at (617) 720-3500 (extension 343).

Respectfully submitted,

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